IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS, **Plaintiff,** **v.** **JON W. DUDAS, et al.,** **Defendants.**	**1:07cv846 (JCC/TRJ)**

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, **d/b/a GLAXOSMITHKLINE, et al.,** **Plaintiffs,** **v.** **JON W. DUDAS, et al.,** **Defendants.**	**1:07cv1008 (JCC/TRJ)**

REPLY IN FURTHER SUPPORT OF GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT

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TABLE OF ABBREVIATIONS FOR CITATIONS TO COURT FILINGS

Abbreviation	Document
GSK SJ Br.	Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
GSK SJ Opp.	GlaxoSmithKline's Opposition to Defendants' Motion for Summary Judgment Against the "GlaxoSmithKline" Plaintiffs, Docket No. 252 in 1:07cv846
Knowles Decl.	Declaration of Sherry M. Knowles, Exhibit 4 (Docket No. 142-11) to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
Manbeck Decl.	Declaration of Harry F. Manbeck, Jr., Exhibit 5 (Docket No. 142-12) to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
Ex. ___ (1-26)	Exhibits to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
PTO SJ Br.	Memorandum in Support of Defendants' Motion for Summary Judgment, Docket No. 141 in 1:07cv846
PTO SJ Opp.	Defendants' Memorandum in Opposition to GlaxoSmithKline's Motion for Summary Judgment, Docket No. 246 in 1:07cv846
PTO Tafas SJ Opp.	Defendants' Memorandum in Opposition to Plaintiff Triantafyllos Tafas's Motion for Summary Judgment, Docket No. 247 in 1:07cv846
AIPLA SJ Br.	Brief of *Amicus Curiae* American Intellectual Property Law Association, Docket No. 185 in 1:07cv846
L. Profs. Br.	Brief of *Amicus Curiae* Intellectual Property, Administrative Law and Public Health Professors in Support of Defendants' Anticipated Motions for Summary Judgment, Docket No. 232 in 1:07cv846
Am. Compl.	Verified Amended Complaint, Docket No. 5 in 1:07cv1008
PTO Answer GSK Am. Compl.	Answer to Plaintiff SmithKline Beecham's Verified Amended Complaint, Docket No. 101 in 1:07cv846
TRO Hr'g Tr.	October 31, 2007 Hearing Transcript, Docket No. 69 in 1:07cv1008

I. INTRODUCTION.

The PTO's opposition to GSK's motion for summary judgment attempts to explain why entering the preliminary injunction was wrong and the agency possesses the full measure of authority it claims, but that opposition only makes further fatal concessions, demonstrating that the Court should grant GSK's motion for summary judgment.

The PTO's primary defense is that the Final Rules are entitled to *Chevron* deference. GSK has repeatedly shown that the PTO is wrong. The Final Rules are substantive, and so are not entitled to deference under *Merck* and *Adams Fruit*. Further, the Final Rules directly conflict with over a century of binding judicial precedent and statutory law. And the PTO seeks to apply these rules retroactively despite conceding that it lacks such authority.

Making matters worse, the Final Rules will trample property rights in patent applications. The PTO disputes this, but in doing so, ignores the Constitution, more recent Supreme Court precedent, and the Patent Act. The PTO also violates due process by trying to impose the hopelessly vague preexamination search requirement on applicants even though an array of "guidance" documents fails to indicate how one could comply with the regulation.

By constitutional command, Congress has the power to "promote the Progress of [the] useful Arts." Using that power, Congress established the patent laws to promote innovation. Because the Final Rules will change the degree of patent protection afforded by those laws and will intrude upon the Judiciary's role to interpret the Patent Act, the rules are not only *ultra vires* and inconsistent with law, but threaten to do great harm to innovation in this country. As a result, GSK respectfully urges the Court to vacate the Final Rules.

II. GSK IS ENTITLED TO JUDGMENT AS A MATTER OF LAW.

A. The Final Rules Are Not Entitled To Deference.

The central issue before the Court is whether the Final Rules are entitled to deference. The answer to that question is a resounding "NO." Despite this, the PTO asserts that the Final Rules fall within its section 2(b)(2) authority. (PTO SJ Br. 14-15.)[1] The PTO's argument fails for several reasons.

First, the Final Rules are substantive because they affect patent applicants' rights and obligations. *See Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (Substantive rules are those that "effect[] a change in existing law or policy which affect[] individual rights and obligations.") (internal quotations omitted). Here, the Final Rules affect GSK's statutory rights by limiting continuing applications, RCEs, and claims under the Patent Act, as demonstrated below and in GSK's summary judgment papers. *See infra* §§ II.B.-II.E.; (*see also* GSK SJ Br. 18-20; GSK SJ Opp. 4-5). Thus, the Final Rules are substantive.

But the PTO lacks substantive rulemaking authority. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).[2] Thus, because the PTO exceeded its limited procedural rulemaking authority by promulgating the substantive Final Rules, the PTO is not entitled to deference. *See Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."); *see also*

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[1] As it does throughout its opposition, the PTO cites to *amicus* briefs, including that of the law professors, as though they are binding authority. (*See, e.g.*, PTO SJ Opp. 5.) Not only is it inappropriate to cite *amicus* briefs in this manner, but, on this point, the law professors ignore *Adams Fruit*, rendering their analysis unhelpful. (*See* GSK SJ Opp. 7.)

[2] The PTO attempts to diminish *Merck*, asserting that the case's discussion of rulemaking authority is *dicta*. (*See* PTO SJ Opp. at 4-5 n.5.) The PTO is mistaken. Both the PTO and the FDA asserted that the PTO's "Final Determination" was entitled to *Chevron* deference. *See Merck*, 80 F.3d at 1549. With the issue put squarely before the court, the Federal Circuit found that the PTO lacked substantive rulemaking authority and that *Chevron* did not apply.

A.T. Massey Coal Co. v. Holland, 472 F.3d 148, 167 (4th Cir. 2006); (GSK SJ Br. 18-19; GSK SJ Opp. 5-6).[3]

The PTO attempts to distinguish *Adams Fruit*, asserting that the case held that "the Court found it inappropriate to consult executive interpretations of the statute" because "'Congress has expressly established the Judiciary and not the Department of Labor as the adjudicator of private rights of action arising under the [federal] statute.'" (PTO SJ Opp. 7 (quoting *Adams Fruit*, 494 U.S. at 650).) Here, Congress has done just that, demonstrating that, even under the PTO's reading of *Adams Fruit*, the PTO is not entitled to deference. More specifically, Congress established the Federal Circuit (and the Judiciary as a whole) to interpret the Patent Act. (*See* GSK SJ Br. 19.)[4] Furthermore, in recent years, Congress has considered granting the PTO such authority, but declined to do so. (GSK SJ Br. 18.)[5] Indeed, on this very issue, Senator Charles Schumer, a member of the Senate Judiciary Committee overseeing Patent Law Reform, in a letter to the PTO, questioned "whether the PTO has the necessary authority" to promulgate the

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[3] The PTO attempts to distinguish *A.T. Massey* as involving a "ministerial" role for the agency. (PTO SJ Opp. 7.) In that case, as here, the agency had limited procedural rulemaking authority, and, when it acted beyond that authority, the Fourth Circuit refused to grant it deference. 472 F.3d at 167.

[4] The PTO asserts that Congress' creation of the Federal Circuit is "simply irrelevant" and that the PTO is "entitled to the same deference from the courts as any other agency." (PTO SJ Opp. 7-8.) GSK does not dispute that the PTO is entitled to deference when it acts within its congressionally delegated authority. But in promulgating the Final Rules, the PTO exceeded its authority and, as in *Adams Fruit*, the PTO is entitled to no deference as a result. Further, the fact that the Federal Circuit has given *Chevron* deference to other agencies when they acted within their authority is irrelevant to the central issue—that the PTO exceeded its authority in promulgating the Final Rules. (PTO SJ Opp. 8.) Also, the Federal Circuit has repeatedly compared the PTO's powers to those of such other agencies and found the PTO's powers lacking in comparison. (GSK SJ Opp. 5 (citing Federal Circuit cases).)

[5] The PTO attempts to minimize Congress' inaction in granting the PTO broader rulemaking authority. (PTO SJ Opp. 8.) But, as the Supreme Court did this past term, it is appropriate to rely on congressional inaction when it signals Congress' satisfaction with the status quo. *See Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.*, 127 S. Ct. 1534, 1540-41 (2007) (highlighting congressional inaction as bearing on a dispute concerning agency authority).

Final Rules. (Ex. 2.) Because the PTO exceeded its authority in promulgating rules that intrude upon the Judiciary's role to interpret the Patent Act, the Final Rules are not entitled to deference. (*See* GSK SJ Br. 18-20; GSK SJ Opp. 4-6.)

Second, the PTO's attempts to place its Final Rules within the *Chevron* framework are unavailing. (*See* PTO SJ Opp. 5-10.) The PTO asserts it is entitled to *Chevron* deference because section 2(b)(2) grants it rulemaking authority. (*See id.* 5-7.) But whether the PTO has ***some*** rulemaking authority is irrelevant. The dispositive fact is that it lacks the ***substantive*** rulemaking authority necessary to pass ***these rules***. *See Merck*, 80 F.3d at 1549-50; (*see also* GSK SJ Opp. 8.) The PTO cannot bootstrap the substantive Final Rules into its confined procedural rulemaking authority. *See Adams Fruit*, 494 U.S. at 650.

The PTO then incorrectly asserts that whether the rules are procedural or substantive is largely irrelevant, because Congress gave it substantive rulemaking authority under section 553 of the APA. (PTO SJ Opp. 4 n.5.) Neither by its plain terms nor by implication does section 2(b)(2)'s reference to section 553 of the APA delegate substantive rulemaking power to the PTO as "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Instead, section 553 merely sets out procedures for notice and comment rulemaking that the PTO may follow, although it is not required to do so in view of its limited procedural authority. Further, binding Federal Circuit precedent contradicts the PTO's new assertion of substantive rulemaking authority. *See Merck*, 80 F.3d at 1549-50; *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007); (*see also* GSK SJ Opp. 8-9).[6]

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[6] As its fallback position, the PTO asserts that the Final Rules are entitled to *Skidmore* deference. (PTO SJ Opp. 10.) GSK has demonstrated that the PTO's *Skidmore* position is equally incorrect. (GSK SJ Opp. 9.) The PTO's citation of *Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400

Third, the cases upon which the PTO relies do not support its substantive power grab. (*See* PTO SJ Br. 15-16.) Instead, the cases discuss procedural rules. *See Lacavera v. Dudas*, 441 F.3d 1380, 1382 (Fed. Cir. 2006); *Stevens v. Tamai*, 366 F.3d 1325, 1332-33 (Fed. Cir. 2004); (*see also* GSK SJ Opp. 9-11 (distinguishing *Lacavera* and *Stevens*)).[7]

Fourth, the PTO attempts to color the Final Rules as procedural, arguing that they do not affect GSK's substantive rights to receive a patent. (PTO SJ Opp. 5, 9-10.) But, as explained above, the Final Rules limit GSK's statutory rights to receive a patent.[8] (*See* GSK SJ Opp. 4-5.)

The PTO further asserts that it can issue procedural regulations, even if they have substantive effects. (PTO SJ Opp. 9-10.) The PTO's assertion directly contradicts its prior representations to this Court that the Final Rules are procedural and have no substantive effects. (*See* GSK SJ Opp. 10-11; TRO Hr'g Tr. 42-43.) Further, the PTO misses the point, as the Final Rules go beyond merely organizing the PTO's internal operations—they alter the rights and obligations of regulated parties. *See infra* §§ II.B.-II.E.; (GSK SJ Br. 14-16, 20-28; GSK SJ Opp. 12-24).[9]

F.3d 1352, 1365 (Fed. Cir. 2005), is unavailing as that case does not involve an *Adams Fruit*-type situation.

[7] The PTO also asserts that similar rules have been upheld as being within its authority to require "additional information." (PTO SJ Opp. 5-6.) However, the cited cases are inapposite as they all deal with 37 C.F.R. § 1.56, which relates to information already known by and available to the applicant. (*See* GSK SJ Opp. 24 n.17.) In fact, one of those cases specifically recognizes that applicants have "no general duty to conduct a prior art search" and, therefore, contradicts the PTO's position. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005).

[8] In its opposition, the PTO states that "[a]ny invention that would have met these criteria before the Final Rules will still meet these criteria after them, and Plaintiffs do not contend otherwise." (PTO SJ Opp. 10.) Since day one GSK has contended, for example, that Final Rule 78 bars GSK from obtaining patents on otherwise patentable inventions under 35 U.S.C. §§ 102 and 103 by preventing GSK from obtaining the benefit of its "stake in the ground." (*See, e.g.*, Am. Compl. ¶¶ 37-40; Knowles Decl. ¶¶ 18-44; GSK SJ Opp. 12-24.)

[9] The PTO relies on *JEM Broadcasting Co. v. FCC*, 22 F.3d 320, 322 (D.C. Cir. 1994), which is distinguishable because the Final Rules are not limited to "weed[ing] out hastily prepared,

Finally, the Final Rules are "inconsistent with law" and, therefore, exceed the PTO's authority under section 2(b)(2). *See infra* §§ II.B., II.C., and II.D.; (GSK SJ Br. 20-28).

B. Final Rule 78 Is Contrary To Established Patent Law.

The PTO's primary argument is that Final Rule 78 passes muster because it is entitled to *Chevron* deference. (*See* PTO SJ Opp. 10-12.) However, as GSK has repeatedly demonstrated, the PTO exceeded its authority in promulgating Final Rule 78, and, therefore, it is not entitled to deference. *See Adams Fruit*, 494 U.S. at 650; *see also supra* § II.A.[10]

The PTO also asserts that it has authority to impose "reasonable conditions" on continuation applications because 35 U.S.C. § 120 allegedly "says nothing" on that issue. Final Rule 78, however, imposes a hard limit, not reasonable conditions. As GSK has explained, the "could not have been submitted" standard amounts to a "physical impossibility" standard, which bars an applicant in almost all circumstances from being granted a third continuing application. (GSK SJ Br. 14-15; Manbeck Decl. ¶ 41); *see supra* § II.D. Moreover, over three decades ago, the *Hogan* court stated that section 120 is "clear and unambiguous": if an application meets the formal requirements of section 120, then the PTO ***shall*** (*i.e.*, must) accord the application the benefit of the earlier filing date. *See In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977); (GSK SJ Br. 20-21; Manbeck Decl. ¶¶ 16-17, 30-31).

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incomplete applications," and *Ranger v. FCC*, 294 F.2d 240 (D.C. Cir. 1961), which is inapposite because the Final Rules do more than merely establish a deadline for filing an application with regulators.

[10] The PTO also asserts it is entitled to deference under *National Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967 (2005), on the basis that an agency may ignore and trump prior judicial interpretations of statutes. (PTO SJ Opp. 11-12 (citing L. Profs. Br. at 10).) But *Brand X* simply does not apply. (*See* GSK SJ Opp. 6-7 n.2.) The PTO also attempts to justify its *Brand X* argument by mischaracterizing *Henriksen* as having cited the lack of an agency rule as "critical" to its determination that the PTO could not restrict continuations. (PTO SJ Opp. 12 (citing *In re Henriksen*, 399 F.2d 253, 262 (C.C.P.A. 1968)).) The *Henriksen* court, however, criticized the PTO for imposing a limit akin to a retroactive rule and then unambiguously stated that ***only*** Congress can limit continuations. 399 F.2d at 261-62.

The PTO further argues that Final Rule 78 is lawful under its belief that it has "inherent authority" to limit continuing applications. (PTO SJ Opp. 12-13 (citing *Bogese II*, 303 F.3d at 1367-68).) But the PTO "has no inherent authority, only that which Congress gives."[11] *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988). And imposing "a limit upon continuing applications is a matter of policy for the Congress"—not the PTO. *Hogan*, 559 F.2d at 604 & n.13 (citing *Henriksen*); *see also Henriksen*, 399 F.2d at 254; *Ex Parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975). The PTO attempts to overcome this, arguing that *Hogan* only addressed the Judiciary's authority to limit applications, not the PTO's power to impose "reasonable conditions." (PTO SJ Opp. 12.) But the *Hogan* court was deciding an appeal from the PTO's Board of Appeals. 559 F.2d at 597. Moreover, the *Hogan* court relied on *Henriksen*, which unambiguously states that "it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction sought by the board is to be imposed." *Henriksen*, 399 F.2d at 262. Thus, *Hogan* and *Henriksen* make clear that the decision to impose any limits, restrictions, or conditions on continuing applications is a policy matter for Congress.

While *Bogese II* allows the PTO to reject applications under prosecution laches on a case-by-case basis, the case expressly bars the PTO from imposing "a mechanical rule" as the PTO has done here. *In re Bogese*, 303 F.3d 1362, 1368 & n.6 (Fed. Cir. 2002). And *Symbol IV* expressly states that "the doctrine should be used sparingly lest statutory provisions be unjustifiably vitiated . . . [and, then,] only in egregious cases." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("*Symbol IV*"). The PTO ignores these pronouncements, and instead argues that it would be "perverse" to allow the PTO to "individually reject each of the plaintiffs' pending applications because they have filed too many," but not allow the PTO to impose the limit of Final Rule 78. (PTO SJ Opp. 13 (citing L. Profs. Br. 7).) Therein lies the PTO's fundamental misunderstanding of its lack of power and the laches doctrine.

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[11] *Bogese II* did not grant the PTO authority that "goes beyond" the context of that case. (*See* PTO SJ Opp. 13.) On the contrary, *Symbol II* and *Symbol IV* confine *Bogese II* to the doctrine of prosecution laches. (*See, e.g.*, GSK SJ Opp. 15-16 & n.11.)

As GSK has shown, prosecution laches does not permit the PTO to reject continuing applications on an across-the-board basis simply because the PTO believes that more than two continuations is "too many." (*See* GSK SJ Opp. 15-16.) Indeed, "[i]t is not the number of continuing applications which is determinative, but the overall course of conduct by an applicant which may result in the forfeiture of a right to a patent." *Hull*, 191 U.S.P.Q. at 160. Thus, the prosecution laches doctrine permits the PTO to reject continuing applications only on a case-by-case basis after a fact-specific determination that the applicant engaged in "unreasonable" and "unexplained" delay in prosecuting its applications. *See Symbol IV*, 422 F.3d at 1385; *see also Bogese II*, 303 F.3d at 1368 n.6, 1369; *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1364 (Fed. Cir. 2002) ("*Symbol II*").

C. Final Rule 114 Contradicts Section 132.

The PTO lacks the authority to limit applicants to one RCE per application family and, therefore, Final Rule 114 is not entitled to deference. (*See* GSK SJ Opp. 17-18.) The PTO continues to mischaracterize the rule as allowing "an applicant who has received a final Office action [to], as a matter of right, file one RCE." (PTO SJ Opp. 14.) But this is not what Final Rule 114 allows; instead, the rule limits applicants to one RCE ***per application family***. (Ex. 1 at 46,737; GSK SJ Opp. 17-18.)

An "application family" comprises a number of individual patent applications. "An application family includes the initial application and its continuation or continuation-in-part applications." (Ex. 1 at 46,737). Yet the phrase "application family" does not appear anywhere in the Patent Act. *See* 35 U.S.C. § 1 *et seq*.

On the contrary, 35 U.S.C. § 132(b)'s RCE provision applies to "all applications," not just one per application family. (*See* GSK SJ Br. 23-25; GSK SJ Opp. 17-18.) Section 132(b) mandates that the PTO "***shall*** prescribe regulations to provide for the ***continued examination of applications*** for patent at the request of the applicant." (Emphasis added.) Thus, by restricting RCEs to one per application family, Final Rule 114 violates the plain language of section 132(b).

The "Effective Date" provision of section 132(b)'s enacting legislation further demonstrates that RCEs are available for all applications rather than one per application family. (*See* GSK SJ Opp. 18.) The PTO argues that the "Effective Date" provision "simply limits RCEs to those applications . . . that were filed after June 8, 1995." (PTO SJ Opp. 14.) Final Rule 114 does not even allow that much, though. Instead, Final Rule 114 limits applicants to one RCE per application family. Thus, Final Rule 114 falls short of what even the PTO concedes to be the bare minimum required under the statute—at least one RCE per application.

The PTO's initial regulations further confirm that the RCE procedure is available for "all applications." (*See* GSK SJ Br. 24-25.) The PTO asserts that its initial regulations did not state that the PTO "could not" impose conditions but that "as a descriptive matter," it simply had not done so. (PTO SJ Opp. 15.) There is nothing in the PTO's initial rules, however, that can be reasonably interpreted to indicate that the PTO possessed but reserved the power to impose conditions on RCEs. The PTO lacked such authority then, and it lacks such authority now.

D. Final Rules 78 And 114 Impose Hard Limits.

The PTO now argues for the first time that GSK's case is not ripe because Final Rules 78 and 114 do not impose a hard limit on continuing applications and RCEs.[12] (PTO SJ Opp. 15.)

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[12] The PTO did not raise ripeness in opposing GSK's request for preliminary relief, in responding to GSK's amended complaint (*see* PTO Answer GSK Am. Compl.), or in its opening summary judgment brief. Now, relying on *amicus* briefs, the PTO asserts GSK's claims are not ripe. The PTO's eleventh-hour ripeness objection lacks credibility.

This case is one that is appropriate for preenforcement judicial review under *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49 (1967). First, GSK presents purely legal issues, and there has been final agency action. Second, delaying review of Final Rules 78 and 114 would impose a hardship on GSK and other patent filers who regularly file continuing applications and RCEs. (*See* GSK SJ Br. 7-12; Knowles Decl. ¶¶ 18-44.) In fact, Final Rules 78 and 114 require GSK and other filers "either to expend non-recoverable resources in complying with a potentially invalid regulation or to risk subjection to costly enforcement processes." *Seegars v. Gonzales*, 396 F.3d 1248, 1253 (D.C. Cir. 2005).

The PTO protests that "GSK cannot seriously contend that the 2 + 1 Rule represents a 'hard limit.'"[13] (PTO SJ Opp. 17.) Yet, the PTO has already conceded that the Final Rules limit continuing applications and RCEs. At the preliminary injunction hearing, the PTO admitted that its goal was "stopping" continuations. (*See* TRO Hr'g Tr. 51:5-11.) And, in public presentations, the PTO expressly admitted it was limiting continuing applications and RCEs. (*See, e.g.*, Ex. 18 at A00432 ("Why Limit Continuations?"); *id.* at A00433 (stating that the rule "[l]imits . . . RCEs"); Ex. 19 at A00264 (stating that the rule "[l]imits the number of . . . RCEs that may be filed by right").)

The *Federal Register* similarly demonstrates that the PTO is imposing a hard limit. In response to numerous requests from commenters on what situations would satisfy the "could not

[13] The PTO attempts to minimize the fact that it is imposing a hard limit by identifying four very rare circumstances in which it allegedly may grant petitions. (PTO SJ Opp. 17.) A closer look, however, reinforces the fact that the petition requirement is a hard limit. Specifically, even in those four circumstances, the PTO erects significant barriers that applicants must overcome before the PTO will even consider granting the petition. (Ex. 1 at 46,773-76.) Indeed, despite those significant barriers, the PTO still refuses to state that it "will" grant those, or any other, petitions. Notably, in the PTO's 10,000-page administrative record, the PTO cannot identify a single instance in which it stated it would grant a petition. In short, as GSK has explained from the beginning, the petition requirement is illusory, and the PTO will deny petitions in almost all circumstances.

have been submitted" standard, the PTO responded that virtually no circumstance would meet this standard. (GSK SJ Br. 14-15.) In fact, the PTO provided many examples of what showings it considered insufficient to grant a petition, including many circumstances under which the Federal Circuit has specifically endorsed continuing applications. (*See* GSK SJ Opp. 12-14; GSK SJ Br. 10, 21; Manbeck Decl. ¶¶ 32, 35, 38.) In sum, the PTO's statements to this Court, in public presentations, and in the *Federal Register* make clear that the PTO intends to deny petitions in almost all circumstances.[14]

In an effort to salvage these rules, the PTO seizes on its use of the word "likely" in the phrase "the Office will likely not grant the petition" in the *Federal Register* (*e.g.*, Ex. 1 at 46,772), as demonstrating that it intends to consider applications on a case-by-case basis. This new argument is inconsistent with the PTO's stated mission of providing applicants with "guidance and certainty." (PTO SJ Opp. 13 (citing L. Profs. Br. 7).) Further, the argument contradicts the PTO's clear pronouncement of the Final Rules' true purpose—"stopping" continuations and reducing its backlog.

E. Final Rules 75 And 265 Are Inconsistent With The Patent Act.

The PTO lacks the authority to limit the number of claims an applicant may prosecute and, thus, Final Rules 75 and 265 are not entitled to deference. (*See* GSK SJ Opp. 19-24.) The PTO, however, contends that Final Rules 75 and 265 do not limit the number of claims; rather, they merely require the submission of "additional information." (PTO SJ Opp. 18-20.) But, as GSK has explained, Final Rule 265's ESD requires much more than mere "additional

[14] GSK still faces an ethical quandary under the PTO's ethics rules by merely filing the petition. (*See* GSK SJ Br. 22; Manbeck Decl. ¶¶ 40-42.) While the PTO criticizes GSK's position, not once has the PTO indicated that it would not seek disciplinary action against those applicants who filed such petitions. Further, the PTO misrepresents the standard as one of "reasonable diligence"—a standard it expressly rejected in favor of its harsh, bright-line "could not have" standard. (Ex. 1 at 46,768-69 (rejecting several proposed alternative standards, including that of "reasonable diligence").)

information." First, the Final Rule unlawfully sends patent applicants on a world-wide, mandatory hunt to identify and review all patents, patent applications, and literature without limitation or regard to cost. (*See* GSK SJ Opp. 22-23.) Contrary to the PTO's assertion that it has the "inherent authority" to require this information (PTO Tafas SJ Opp. 3), the PTO has no such authority to require applicants to conduct a prior art search. *See Bruno Indep. Living*, 394 F.3d at 1351 n.4 ("[T]here is no general duty to conduct a prior art search . . . ."); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) ("[A]n applicant for patent . . . has no duty to conduct a prior art search . . . ."); (*see also* GSK SJ Opp. 22-24 & n.17).

Second, the ESD unlawfully shifts to the applicant both the burden of examination and proving patentability. (*See* GSK SJ Opp. 23-24.) The PTO asserts that the ESD does not require applicants to come forward with a *prima facie* case of patentability. (*See* PTO Tafas SJ Opp. 2.) But the plain language of the ESD requires applicants to provide, among other things, a "detailed explanation" of "how each of the independent claims ***is patentable over*** the cited references." (Ex. 1 at 46,842 (Final Rule 265(a)(3)-(5)) (emphasis added).) Thus, the ESD violates at least 35 U.S.C. §§ 102, 103, and 131, which unambiguously place the burden of examination on the PTO and require the PTO to grant a patent unless it makes a *prima facie* case of unpatentability. (*See* GSK SJ Opp. 23-24.)

The PTO also attempts to justify the ESD by likening it to the PTO's Accelerated Examination Program ("AEP"). (PTO SJ Opp. 18.) Critically, though, the AEP is a ***voluntary*** program in which an applicant willingly surrenders substantive rights in exchange for expedited examination of its application. (*See* Ex. 1 at 46,796 (distinguishing the ESD from the AEP because "an ***optional*** procedure for [an] applicant to advance the application out of turn would not result in the desired gains in efficiency and quality") (emphasis added).) Thus, the AEP is not at all like the ESD and has no bearing on the lawfulness of the ESD.

The PTO concedes that applicants have a statutory right under 35 U.S.C. § 112, ¶ 2 to determine the number of claims they file. (PTO SJ Opp. 19); *see also In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970).[15] The PTO further concedes that rejecting claims as being unreasonable in number under the doctrine of undue multiplicity is a "***substantive ground***." (PTO SJ Opp. 19 (emphasis added).) It then unsuccessfully attempts to distinguish that "substantive ground" and four cases—*Wakefield*, *Flint*, *Chandler,* and *Clark*—on two fatally flawed bases. (*Id*. 18-19.) First, the PTO argues that the Final Rules do not "purport to 'determine the necessary number' . . . of applicants' claims," but merely require the applicant to submit "additional information." (*Id.* 19.) As demonstrated above, Final Rules 75 and 265 do so much more than that. Thus, the PTO has clearly made the "substantive judgment" to impose a 5/25 limit. (*Id*.)

Second, the PTO argues that ***rejecting*** claims for undue multiplicity is substantive, whereas ***abandoning*** an application because it exceeds the 5/25 limit is procedural.[16] (*Id*.) There is no meaningful difference between the two. Indeed, abandonment of an entire application—which strips an applicant of all of his claims—is much harsher than a piecemeal rejection of individual claims for undue multiplicity. Moreover, both actions affect an applicant's statutory right to determine the number of claims necessary to protect his invention properly. Worse, unlike a rejection for undue multiplicity, the Final Rules abandon applications in a mechanical fashion, failing to take into account the relevant facts and circumstances of each individual case. (*See* GSK SJ Br. 27); *see In re Flint*, 411 F.2d 1353, 1357 (C.C.P.A. 1969) (requiring that the PTO assess the propriety of the number of claims on a case-by-case basis).

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[15] The PTO relies on *In re Rubinfield*, 270 F.2d 391 (C.C.P.A. 1959), a design patent case, to argue that it has the authority to limit the number of claims in a utility patent application. (PTO SJ Opp. 20.) As GSK has explained, *Rubinfield* is inapt. (*See* GSK SJ Opp. 21-22.)

[16] The PTO also asserts that Final Rules 75 and 265 are procedural because there is a "critical distinction" between how one seeks relief from a rejection and from an abandonment. But that distinction is irrelevant because the proper inquiry is whether the rules affect an applicant's rights and obligations. As GSK has shown, Final Rules 75 and 265 do so and are substantive. (*See, e.g.*, GSK SJ Br. 25-28; GSK SJ Opp. 4-5.)

In short, as the PTO intended and has acknowledged, the ESD creates a *de facto* limit on the number of claims applicants may seek to prosecute. (GSK SJ Br. 25-28; GSK SJ Opp. 22-24.) Thus, Final Rules 75 and 265 are contrary to law and should be vacated.

F. The ESD's Preexamination Search Requirement Is Incomprehensibly Vague.

The PTO raises two arguments in support of its assertion that the ESD is not unconstitutionally vague: (1) that vagueness doctrines do not apply to the ESD and (2) that the ESD's search requirement is not vague. (PTO SJ Opp. 37-42.) Both arguments fail.

First, the PTO's view that due process applies only to regulations "prohibiting conduct or regulating First Amendment rights" is incorrect. (*See* GSK SJ Opp. 24-26.) Rather, due process specifies that regulations must provide "fair warning." (*Id.*) The PTO overlooks the "fair warning" doctrine even though both parties quoted from the fair warning discussion. *Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Review Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997); (GSK SJ Opp. 25-26 (quoting *Freeman*); PTO SJ Br. 55 (same); PTO SJ Opp. 38 (same)). Moreover, the Court relied on the fair warning doctrine, and *Freeman* in particular, in finding that GSK is likely to succeed in establishing that the Final Rules are vague. *See GlaxoSmithKline v. Dudas*, 511 F. Supp. 2d 652, 667-68 (E.D. Va. 2007).

Freeman itself resolves the issue. There, the challenged regulation provided that "[a]ll mine structures, enclosures, or other facilities . . . shall be maintained in good repair to prevent accidents and injuries to employees." *Freeman*, 108 F.3d at 362 (internal quotations omitted). While the court denied the challenge, it did so because the regulation gave sufficient notice as to the conduct required, not on the basis of the PTO's "prohibited conduct or speech" test. *See id.*

A second case that both sides invoke, *General Electric Co. v. EPA*, 53 F.3d 1324 (D.C. Cir. 1995), also confirms that GSK is correct. (*See* PTO SJ Opp. 40; GSK SJ Opp. 26.) *General Electric* involved a challenge to a statute mandating compliance with chemical disposal requirements. 53 F.3d at 1326. While the court noted that "it is in the context of criminal liability that this 'no punishment without notice' rule is most commonly applied," the court noted that it had long "recognized this 'fair notice' requirement in the civil administrative context." *Id.* at 1329. *General Electric* further confirms that deprivation of "property"—not just one's freedom or speech rights—is sufficient to invoke due process protections.[17] *Id.* at 1328-29. Here, Final Rule 265 will regulate conduct and deprive applicants of property. Thus, due process requires that applicants be given fair notice.

Second, the PTO's argument that the ESD's search requirement is not vague is likewise incorrect. Despite the PTO's continued reliance on a dizzying array of "guidance" documents as "clarifying" the rule's vagueness (*see* PTO SJ Opp. 40-42), the ESD remains fatally vague (GSK SJ Br. 28-31; GSK SJ Opp. 27-28). The PTO's reliance on a kitchen-sink approach reaffirms that Final Rule 265 is vague and fails to provide fair notice. *See Radio Athens, Inc. v. FCC*, 401 F.2d 398, 404 (D.C. Cir. 1968) (rejecting the supposedly clarifying interpretations because the agency should have accomplished the result through rulemaking; "[w]hen the sanction is as drastic as dismissal [of the application] . . . elementary fairness compels clarity in the notice of the material required as a condition for consideration").

[17] *Freeman* and *General Electric* are consistent with a long line of cases that examine regulations for compliance under the fair warning doctrine. (*See* GSK SJ Opp. 25-26 (citing cases).) The PTO's reliance on *Nyeholt v. Sec'y of the Veterans Affairs*, 298 F.3d 1350, 1357 (Fed. Cir. 2002) is unavailing. GSK has already distinguished *Nyeholt*. (GSK SJ Opp. 26 n.19.) In addition, patent applications are property (*id.* at 35-36), whereas *Nyeholt* involved disability benefits for liver ailments, *see Nyeholt*, 298 F.3d at 1357.

As with continuing applications and RCEs, the PTO asserts for the first time that GSK's vagueness claim is not ripe because the PTO "will provide additional information" to applicants who file non-compliant ESDs. (PTO SJ Opp. 39-40.) The PTO's eleventh-hour argument, however, only bolsters GSK's position. Both parties agree that GSK's challenge to the ESD is purely legal. The ESD's vagueness imposes a hardship because GSK has already shown that it does not know how to comply with the preexamination search requirement. The fact that the PTO admits it will need to "provide additional information" (PTO SJ Opp. 39), in addition to Final Rule 265 and the PTO's litany of extrinsic sources, reaffirms that the search requirement is incomprehensibly vague and ripe for review. *See Abbott Labs.*, 387 U.S. at 149-53 (rejecting the government's ripeness argument because the "issue tendered" was "purely legal," the regulations were "final" and had "a direct effect on the day-to-day business of all prescription drug companies," and "[t]o require [petitioners] to challenge these regulations only as a defense to an action . . . might harm them severely and unnecessarily").[18]

Finally, the PTO argues that because "practitioners and applicants are familiar with" prior art searches, the Court should reject GSK's due process challenge. (PTO SJ Opp. 42.) While practitioners may have conducted prior art searches in the past, they did so when they wanted and as they saw fit. Conversely, the ESD requires applicants to conduct prior art searches in certain instances and to do so according to a new and incomprehensible procedure. (*See* GSK SJ Br. 28-31; GSK SJ Opp. 27-28.) Thus, this newfound argument is irrelevant.

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[18] The PTO's other ripeness cases are distinguishable. *See Reg'l Mgmt. Corp. v. Legal Servs. Corp.*, 186 F.3d 457, 465 (4th Cir. 1999) (claim not ripe where there was "no reason to think that [the challenged] policy will affect [the plaintiff]-or, for that matter, anyone else"); *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998) (claim not ripe where provision did "not command anyone to do anything or to refrain from doing anything," or "create [any] legal rights or obligations," or inflict "practical harm" on plaintiffs).

G. The Final Rules Are Retroactive And Unlawful Under *Bowen*.

As GSK has explained, the PTO enacted the Final Rules to address a growing "backlog." By definition this violates the retroactivity doctrine, particularly now that the PTO admits it lacks congressional authorization to promulgate retroactive rules. (*See* GSK SJ Opp. 30.) Moreover, the PTO finally concedes that the "Final Rules ***in some ways*** apply to pending applications," but argues that this fact "do[es] not automatically render them retroactive." (PTO SJ Opp. 26 (emphasis added).) The PTO argues that because the Final Rules "have future effect," they "do not exceed the USPTO's rulemaking authority under *Bowen*." (*Id.*) While the Final Rules may "have [some] future effect," that does not preclude their invalidation under *Landgraf* and *Bowen*. Instead, the proper test is "whether the new provision attaches new legal consequences to events completed before its enactment." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 252-54, 269-70, 293 (1994) (barring retroactive application of damages provisions as applied to cases arising ***before*** their enactment). This requires determining whether the Final Rules "impair rights a party possessed when he acted" or "impose new duties with respect to transactions already completed." *Id*. at 280.[19]

1. The Final Rules Impose New Duties On Completed Transactions.

The PTO asserts that the Final Rules do not impose new duties, but rather require new mechanisms to advance existing duties. (PTO SJ Opp. 26-27.) The PTO constructs this faulty conclusion, not from statutes or case law, but from its ethics rules. For example, the PTO invokes existing discretion to require applicants to perform preexamination prior art searches because its ethics rules "preclude[] a practitioner from handling a legal matter without

[19] In its opposition, the PTO mistakenly asserts that GSK must show that the Final Rules attach "new legal consequences," in addition to showing that the Final Rules impose new duties. (PTO SJ Opp. 28 (citing *Landgraf*).) New duties with respect to completed transactions is not a requirement separate from "new legal consequences," but merely one factor in showing that "new legal consequences" have attached. *See Landgraf*, 511 U.S. at 280.

preparation adequate in the circumstances." (PTO SJ Opp. 27-28 (citing a law journal article and 37 C.F.R. § 10.77(b)).) But the Federal Circuit has made clear that no such duty exists. *See Bruno Indep. Living*, 394 F.3d at 1351 n.4 ("[T]here is no general duty to conduct a prior art search . . . ."); *Am. Hoist & Derrick*, 725 F.2d at 1362 ("[A]n applicant for patent . . . has no duty to conduct a prior art search . . . ."). The PTO also points to its ethics rules to support its claim of preexisting discretion to limit continuing applications and RCEs. (PTO SJ Opp. 27.) This too contradicts binding Federal Circuit precedent allowing continuations where the Final Rules bar them. (GSK SJ Br. 21-23; GSK SJ Opp. 13-14.)

Moreover, the PTO's assertion that it is not imposing new duties contradicts its own positions in this litigation where it has openly trumpeted the new duties that the Final Rules impose: applicants must, among other things, (i) follow a new "benchmark . . . ***rather*** than using limitless continuation applications" (PTO SJ Br. 1 (emphasis added)), (ii) provide "***greater*** assistance . . . through prior art searches and analysis" (*id.* (emphasis added)), (iii) follow new requirements that mandate "prompt presentation of claims, argument, and evidence" (*id.* at 8), (iv) file a "petition and showing" where none was required before (*id.* at 9), and (v) "provide an [ESD] which must contain information about the claims" where none was required before (*id.* at 10). The Final Rules undeniably impose new duties. (*See* GSK SJ Br. 32; GSK SJ Opp. 33.)

The PTO also incorrectly asserts that any new duties do not affect transactions already completed because the filing of a patent application is not a completed transaction. (PTO SJ Opp. 28.) The PTO's argument fails because, among other reasons, it does not dispute that the publication of patent applications is a transaction already completed that gives applicants rights under 35 U.S.C. § 154(d) of the Patent Act. (*See* GSK SJ Br. 32-33; GSK SJ Opp. 30-34.)

2. The Final Rules Impair Rights Applicants Possess Under The Current Regulatory Regime.

The PTO asserts that the Final Rules do not impair rights, because (1) the Final Rules do not impact GSK's loss of trade secret rights any differently than the old rules; and (2) GSK has no right to prosecute applications in a manner the courts have endorsed for over 100 years. (PTO SJ Opp. 29-31.) The PTO reasserts that GSK is "choosing" to surrender its trade secrets by filing applications in foreign countries and that, as a result, the PTO's mid-stream change in rules has not trampled property rights. (PTO SJ Opp. 29.) As GSK has demonstrated, the PTO's position is decidedly incorrect. (GSK SJ Opp. 33-34.) GSK files patent applications in a bargained-for-exchange; GSK has disclosed its trade secrets in exchange for the right to fully protect those inventions. (GSK SJ Br. 32-33; GSK SJ Opp. 30.) This bargained-for exchange is in no way conditioned on GSK seeking only domestic patents. Through the Final Rules, however, the PTO attempts to renege on its half of the bargain.[20]

Finally, the PTO asserts that GSK's practices are inconsistent with the Patent Act and that GSK "cannot [] claim a 'right' at variance with the law." (PTO SJ Opp. 30.) As GSK has repeatedly demonstrated, unlike the Final Rules, its patent prosecution practices are consistent with over a century of law.[21] Thus, GSK's patent prosecution methods are not "at variance with the law." Instead, it is the PTO's Final Rules that retroactively destroy preexisting rights in trade secrets, patent applications, and the congressionally delineated statutory path to a patent.

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[20] Moreover, inventors would not invest the time and expense required to innovate if others could reverse engineer the invention and freely sell it "abroad"—this fact makes overseas filings an integral aspect of the typical patent prosecution process. Indeed, the PTO's misunderstanding of innovation and patenting strategies makes these rules less lawful, and more capricious, than GSK imagined. (*See* AIPLA SJ Br. 16-17.)

[21] The PTO asserts that GSK's failure to have already claimed all of the inventions disclosed in its presently pending applications somehow demonstrates GSK deems those unclaimed inventions "unworthy." (PTO SJ Opp. 30.) However, because the Final Rules have been enjoined, there would be no reason for GSK to deviate from its existing lawful methods of filing for patents and claiming inventions.

H. The PTO's Failure To Adequately Consider The Final Rules' Takings Implications Was Arbitrary, Capricious, And Contrary To Law.

The PTO argues that GSK's takings claim fails for three reasons: (1) the PTO adequately considered the takings issue; (2) applicants lack property rights in patent applications; and (3) the Final Rules do not effect a taking. (PTO SJ Opp. 33-37.) As GSK has shown, the PTO is mistaken on all three points.[22] (*See* GSK SJ Br. 34-36; GSK SJ Opp. 35-36.)

First, the PTO argues that an agency can only be reversed on arbitrary and capricious grounds if it "***entirely*** failed to consider an important aspect of the problem." (PTO SJ Opp. 31-32 (quoting *Motor Vehicles Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)) (emphasis added by PTO).) According to the PTO, as long as it said ***something*** in the rulemaking rejecting takings claims, its explanation was sufficient. But the PTO's conclusion is contrary to both *State Farm* and *National Wildlife Federation v. ICC*, 850 F.2d 694, 705 (1988). In using the word "entirely," the Supreme Court implicated the agency's ***entire*** failure to recognize "an important ***aspect*** of the problem," not the whole problem itself. Thus, agencies must still ***adequately*** consider takings issues presented to them for decision. *See State Farm*, 463 U.S. at 34 (finding arbitrary and capricious rulemaking because "the agency failed to present an adequate basis and explanation for rescinding the passive restraint requirement"); *see also Nat'l Wildlife*, 850 F.2d at 705-08 (remanding the ICC's takings analysis because it was prematurely truncated).

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[22] The PTO attempts to link GSK's takings argument to its retroactivity argument. The PTO claims that GSK has conceded that if its retroactivity claim fails, then its takings claim fails. (*See* PTO SJ Opp. 32-33.) GSK nowhere conceded any such point. While takings and retroactivity claims may be related, they remain separate legal theories. *See, e.g.*, *E. Enters. v. Apfel*, 524 U.S. 498 (1998) (Plurality decision created where four Justices concluded a statute was a taking, and one concluded it was retroactive and so void.).

Here, the record is clear that the PTO failed to adequately consider the takings issue. (GSK SJ Br. 36-39.) As it did then and continues to do now, the PTO refuses to even acknowledge that patent applications are property. Instead, the PTO continues to rely on two FCC cases to support its position. (PTO SJ Opp. 32-33.) Each of the FCC cases, however, involves an application to use publicly owned airwaves, which is not property. *See Cmty. TV, Inc. v. FCC*, 216 F.3d 1133 (D.C. Cir. 2000); *Chadmoore Commc'ns, Inc. v. FCC*, 113 F.3d 235 (D.C. Cir. 1997). Conversely, here, a patent application is itself property. (GSK SJ Br. 34-35.) Moreover, the PTO did not consider, let alone conduct a takings analysis under, either *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992), or *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104 (1978).[23] In short, the PTO did not adequately consider the takings issue during its rulemaking.

Second, the PTO reasserts that patent applications lack property rights. (PTO SJ Opp. 32-33.) The PTO relies on its post-rulemaking argument that *Marsh v. Nichols, Shepherd, & Co.*, 128 U.S. 605, 612 (1888), stated there were no rights in patent applications.[24] (PTO SJ Opp. 32-33.) While that may have been the law 120 years ago, the PTO's arguments fail to account for the fact that the law has evolved in light of modern conditions. (*See* GSK SJ Br. 35 n.7.) Notably, patent applications meet and exceed the indicia of property that the Supreme Court found sufficient to warrant constitutional protection in *Ruckelshaus v. Monsanto Co.*, 467

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[23] The PTO now argues that the Final Rules' suggested restriction requirements ("SRRs") render a *Lucas* taking an impossibility. (*See* PTO SJ Opp. 35-36.) But that is a *post hoc* rationalization, because the PTO never pointed to SRRs in the regulatory preamble as an answer to any takings concerns raised by commenters. *See West Penn Power Co. v. NLRB*, 394 F.3d 233, 259 (4th Cir. 2005). Moreover, the PTO's analysis is flawed as it is based on its view that GSK is violating the PTO's ethics rules by not immediately claiming every conceivable invention disclosed in an application. The PTO is thus wrong because GSK's method of filing applications for patents and claiming its inventions is entirely consistent with over a century of law. *See supra* § II.G.2.

[24] The PTO's argument regarding *Marsh* and its contention that section 261 does not give rise to property rights are *post hoc* rationalizations and, thus, must be ignored on review.

U.S. 986 (1984). (*See* GSK SJ Br. 34-35.) Further, the PTO continues to ignore that 35 U.S.C. §§ 154(d) and 261, both of which Congress enacted well after *Marsh*, give applicants property rights in applications. (*See id.*) Finally, applications can form the *res* of a trust, pass to the trustee in bankruptcy, and are taxable property. (*See id.*)

Additionally, the PTO argues that because some takings problems result from the fact that the Final Rules impose "hard limitations," GSK improperly exceeded the bounds of a facial challenge. (*See* PTO SJ Opp. 35.) That is wrong for two reasons. GSK has already shown that the Final Rules impose hard limits and that this case cries out for preenforcement review. *See supra* § II.D. And given the PTO's failure to properly consider the takings issue, it is entirely appropriate for the Court to remand the rules to the PTO based on GSK's challenge. *See Nat'l Wildlife*, 850 F.2d at 698 (remanding rules to the ICC based on plaintiff's challenge that the rules, "as applied to her property," would work an unconstitutional taking).

Finally, the PTO invokes 5 U.S.C. § 706 and argues that its failure to adequately consider takings issues is harmless as the Final Rules do not effect a taking. (*See* PTO SJ Opp. 33.) There is nothing harmless, however, about the PTO's fundamentally flawed takings analysis. Thus, as in *National Wildlife*, remand is required because "[i]t is appropriate for the [agency] to resolve [the] 'takings' question ***in the first instance***, free of the error that caused it to prematurely to truncate its analysis in the proceeding below." 850 F.2d at 705 (emphasis added).

I. Final Rule 75 Is Not A Logical Outgrowth Of Proposed Rule 75.

The PTO's primary argument against GSK's logical outgrowth claim is that Final Rule 75 is procedural. (PTO SJ Opp. 42.) As GSK has demonstrated, though, the Final Rules, including Final Rule 75, are substantive. *See supra* § I.A.; (*see also* GSK SJ Br. 18-20; GSK SJ Opp. 4-5.) Therefore, the PTO's primary argument fails.

The PTO also asserts that Final Rule 75's cap on the total number of claims is a logical outgrowth of the proposed rule, which had no such cap. (PTO SJ Opp. 42-45.) To get there, the PTO argues that the change was reasonably foreseeable because its claims-related Notice of Proposed Rulemaking ("NPRM 2") referred to a 1998 proposal to limit the total number of claims. (PTO SJ Opp. 43.) The PTO, however, abandoned the 1998 proposal in response to strong opposition and expressly indicated in NPRM 2 that it was not considering a limit on the total number of clams. (GSK SJ Opp. 40.) Because regulated parties could not reasonably foresee the PTO's flip-flop, Final Rule 75 must be vacated. *See Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996, 998 (D.C. Cir. 2005).

The PTO contends that its approach was "consistent" throughout the rulemaking process. (PTO SJ Opp. 42-43.) The PTO attempts to build "consistency" by characterizing its focus as always on the "threshold number of claims." (*Id.* at 45.) Significantly, however, the proposed rule did not limit the total number of claims. Instead, it allowed an unlimited number of claims so long as the application had fewer than ten designated claims. (Ex. 7 at 67.) Thus, proposed and Final Rule 75 are not consistent. (GSK SJ Br. at 39-40.)[25]

Contrary to the PTO's characterization, GSK's primary argument is not that an 1800% increase in affected applications renders Final Rule 75 unlawful. Rather, the substantial increase is compelling evidence that the PTO's changes to Rule 75 were not "reasonably foreseeable." (*See* GSK SJ Br. 40-41.) The PTO asserts that GSK compared "apples and oranges," but both NPRM 2 and the Final Rules analyze Rule 75's limit in statistically similar terms—the percentage of applications that would be subject to the ESD requirement. (*Compare* Ex. 1 at

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[25] Many of the cases that the PTO cites are easily distinguishable. (*See* GSK SJ Opp. 41 n.33.) One such case, however, *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098 (4th Cir. 1985), actually undermines the PTO and requires vacating Final Rule 75, as the PTO "dramatically altered the proposed rule." *See* 755 F.2d at 1101, 1103; (*see also* GSK SJ Opp. 42).

46,788 *with* Ex. 7 at 66.) The PTO asserts that Proposed Rule 75 would have "affected" many more than 1.2% of all applications. (PTO SJ Opp. 43-44.) But in making that argument, the PTO confuses applications affected by the ESD requirement—as GSK and the Federal Register used that term—with applications affected by the requirement to designate "representative" claims—a wholly irrelevant inquiry. Further, the PTO's attempt to change the percentage of applications affected by the proposed rule is devoid of any record support. In sum, the PTO's *post hoc*, litigation-driven arguments are not only improper, but also unsupported.

J. The Final Rules Are Arbitrary And Capricious.

The PTO fundamentally errs in its defense against GSK's arbitrary and capricious claim. *First*, contrary to the PTO's assertions, *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), and *Prill v. NLRB*, 755 F.2d 941 (D.C. Cir. 1985), fully apply to rulemaking challenges when the agency misperceives the limits of its authority. *See, e.g.*, *Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1029 (D.C. Cir. 2000) (relying on *Chenery* and *Prill* when rejecting agency's rulemaking); *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) (relying on *Chenery* in finding that FDA's decision should be vacated); *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 n.3 (D.C. Cir. 1998) (recognizing that courts refer to this principle as arbitrary and capricious within the meaning of section 706(2) of the APA). Because the PTO misperceived the limits of its authority, the Final Rules are arbitrary and capricious.

Second, given the PTO's foundational errors, it is no surprise that it also made numerous fact-related errors. (*See* GSK SJ Br. 41-45; GSK SJ Opp. 42-45.) Nevertheless, the focus here should be on the PTO's model. In opposing GSK's request for preliminary relief, the PTO pointed to a single model—A05645—as supporting the Final Rules. (*See* PTO TRO Opp. 32.) Now, the PTO asserts that A05645 "was not even created for purposes of supporting this rulemaking." (PTO SJ Opp. 21, 25-26 n.19.) This ***fatal admission*** dooms the Final Rules. *See*, *e.g.*, *Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 632 (D.C. Cir. 2000) (reversing FCC action because the Commission nowhere relied previously on the ground it was now citing to justify its decision) (citing *Chenery*).

The PTO relies on several cases that defer to sophisticated agency modeling or where models were impossible to devise. (*See* PTO SJ Opp. 23.) Those cases are inapposite. In contrast to the intricate models that agencies must and do routinely prepare and release for comment and critique, the PTO's budget model is extremely primitive and based on assumptions that the PTO only now attempts to explain.[26] (*See* GSK SJ Br. 42-45.) In short, the PTO's model is clearly deficient. *See U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1008 (D.C. Cir. 2002) ("When an agency uses a computer model, it must explain the assumptions and methodology used in preparing the model and, if the methodology is challenged, must provide a complete analytic defense.") (internal quotations omitted); *see also Owner-Operator*, 494 F.3d at 199. Thus, the Final Rules are arbitrary and capricious and must be vacated.

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[26] The PTO asserts that GSK relies upon a case allowing the PTO to plug any gaps in explanation for its modeling once litigation begins. (*See* PTO SJ Opp. 22-23 n.16 (citing *Owner-Operator Indep. Driver Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 204 (D.C. Cir. 2007)).) The PTO plainly misreads *Owner-Operator*. *See* 494 F.3d at 204 n.4 ("Whatever the merits of the agency's averaging methodology, we cannot affirm on the basis of a *post-hoc* explanation by agency counsel.").

III. CONCLUSION.

For the reasons sets forth herein and in its related papers, GSK respectfully requests that the Court enter judgment that the Final Rules are invalid, vacate the Final Rules, and grant a permanent injunction against their enforcement.

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Respectfully submitted,

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